Alaina M. Stedillie (Wyoming Bar No. 6-4327)

astedillie@crowleyfleck.com

CROWLEY | FLECK

111 W 2nd St. #220

Casper, WY 82601

Telephone: (307) 265-2279 Facsimile: (307) 265-2307

Brian N. Platt (pro hac vice forthcoming)

bplatt@wnlaw.com

Collin D. Hansen (pro hac vice forthcoming)

chansen@wnlaw.com

WORKMAN NYDEGGER

60 East South Temple Suite 1000

Salt Lake City, UT 84111 Telephone: (801) 533-9800 Facsimile: (801) 328-1707

Counsel for Plaintiff Axcess Global Sciences, LLC

IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF WYOMING

AXCESS GLOBAL SCIENCES, LLC, and PRUVIT VENTURES, INC.,) Civil No:
Plaintiffs,)))
VS.)
VITAL HEALTH INTERNATIONAL LLC,)))
Defendant.)
)
)

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Axcess Global Sciences, LLC ("AGS") and Pruvit Ventures, Inc. ("Pruvit" and collectively, "Plaintiffs") complain and allege as follows against Defendant Vital Health International LLC ("Vital Health" or "Defendant").

NATURE OF THE CLAIMS

- 1. This is an action for patent infringement. The Plaintiffs allege that Defendant infringes U.S. Patent Nos. 10,292,952 (the "'952 Patent"), 11,020,362 (the "'362 Patent"), and 11,241,403 (the "'403 Patent"), titled Mixed salt compositions for maintaining or restoring electrolyte balance while producing elevated and sustained ketosis" and "Beta-hydroxybutyrate mixed salt compositions and methods of use," respectively (collectively, the "Asserted Patents"). The Asserted Patents are attached as Exhibits A, B, and C.
- 2. Plaintiff Pruvit is the exclusive sublicensee of the Asserted Patents in the relevant field of use.

THE PARTIES

- 3. Plaintiff AGS is a Utah limited liability company with a principal place of business at 2157 Lincoln Street, Salt Lake City, UT 84106.
- 4. Plaintiff Pruvit Ventures, Inc. is a corporation organized under the laws of the State of Texas with its principal place of business at 901 Sam Rayburn Highway, Melissa, TX 75454.
- 5. Defendant Vital Health International LLC is a Wyoming limited liability company with its principal places of business at 1021 E Lincolnway Suite #6227, Cheyenne, Wyoming 82001.

JURISDICTION

- 6. This Court has subject matter jurisdiction under 28 U.S.C. § 1331 (federal question), 28 U.S.C. § 1338(a) (any Act of Congress relating to patents or trademarks), and 28 U.S.C. § 1367 (supplemental jurisdiction).
- 7. This Court has personal jurisdiction over the Defendant because it resides in this Judicial District, is registered to do business in this District, maintains its registered agent in this district, and maintains its principal place of business in this Judicial District. In addition, the Defendant has committed a substantial portion of the infringements giving rise to this action from this District and while holding itself out as resident in this District. In addition, the Defendants have committed and continue to commit acts of patent infringement in violation of 35 U.S.C. § 271 in or from this Judicial District. Moreover, on information and belief, the Defendant places infringing products into the stream of commerce with the knowledge or understanding that such products are sold in the State of Wyoming and in this Judicial District. The acts by the Defendant causes substantial injury to the Plaintiffs in this Judicial District and elsewhere, and the Defendant derives substantial revenue in this Judicial District from its sale of infringing products within this Judicial District and throughout the United States based on interstate and international commerce directed to and from this Judicial District.
- 8. Venue is proper in this Judicial District pursuant to 28 U.S.C. § 1391, at least because Defendant resides in this District, is registered to do business in this District, has a registered agent in this district, has a principal office in this District, and has committed a substantial portion of the infringements and other misdeeds giving rise to this action from within this District.

9. The Defendant's business webpage, located at https://vitalhealthglobal.com/, lists its principal place of business as located in Cheyenne, Wyoming.



https://vitalhealthglobal.com/

10. Accordingly, the Court has personal jurisdiction over the Defendants and venue is proper in this Judicial District.

BACKGROUND

11. Plaintiff AGS is an innovator in the field of exogenous ketones and ketogenic precursor supplement products. In particular, AGS has developed a line of products containing novel formulations of the health supplement Beta-Hydroxybutyrate ("BHB"). These products aid the body in producing and sustaining elevated levels of ketone bodies in the blood and assist in the body's transition into nutritional ketosis.

- 12. Plaintiff is the premier provider of BHB supplements in the United States and around the world. Plaintiff's quality products can be found online via its own website, through third-party retailers, and in brick-and-mortar stores across the country like Walmart, Target, Walgreens, CVS, and more.
- 13. The Defendant markets, sells, and offers for sale the supplement products known as KETOKAFE-BHB (the "Accused Products"), which infringe the Asserted Patents, in the United States. The Accused Products are depicted below:



V KETOKAFE-BHB





https://vitalhealthglobal.com/usa/en/productos.html (See Exhibits D, E)

14. The Defendant advertises that the Accused Products are imported into the United States and are distributed by the Defendant from its headquarters in Wyoming:



https://vitalhealthglobal.com/usa/en/productos.html (See Exhibits E)

15. The Defendant makes, uses, advertises, imports, offers for sale, and/or sells the Accused Products with BHB formulations that infringe Plaintiff's exclusive rights in the Asserted Patents.

16. Plaintiffs conducted independent, third-party testing of the Defendant's products to confirm the ingredients used in the Accused Products. Those test results are shown below and attached as Exhibit F.

Work Order: CHSG240322-007 Axcess Global Sciences LLC Received Date: 03/22/2024 Client: 8688 Ruffian Lane, Suite C

P.O. #: Newburgh, IN 47630

Client Contact: Pam Peach

Comments:

Sample Num: 24CH03183 Lot Number: KETOK004

Client Sample Num: MexicoCoffe1 KetoKafe
Comments: Serving Size: 3g

Method Reference BCAL-DV-AMP052 HPLC	Result 561	Unit	Analysis Date	Approval Date
BCAL-DV-AMP052 HPLC	561			
	301	mg/svg	04/03/2024	04/05/2024
BCAL-DV-AMP051	30.5	mg/svg	03/26/2024	04/08/2024
BCAL-DV-AMP051 and BCAL-DV-AMP052	188	mg/svg	04/05/2024	04/05/2024
BCAL-DV-AMP051	22.3	mg/svg	03/26/2024	04/08/2024
BCAL-DV-AMP051 and BCAL-DV-AMP052	212	mg/svg	04/05/2024	04/05/2024
BCAL-DV-AMP051	90.2	mg/svg	03/26/2024	04/08/2024
BCAL-DV-AMP051	31.2	mg/svg	03/26/2024	04/08/2024
BCAL-DV-AMP051 and BCAL-DV-AMP052	171	mg/svg	04/05/2024	04/05/2024
	BCAL-DV-AMP051 and BCAL-DV-AMP052 BCAL-DV-AMP051 BCAL-DV-AMP051 and BCAL-DV-AMP052 BCAL-DV-AMP051 BCAL-DV-AMP051	BCAL-DV-AMP051 and BCAL-DV-AMP052 BCAL-DV-AMP051 22.3 BCAL-DV-AMP051 and 212 BCAL-DV-AMP052 BCAL-DV-AMP051 90.2 BCAL-DV-AMP051 31.2 BCAL-DV-AMP051 and 171	BCAL-DV-AMP051 and BCAL-DV-AMP052 188 mg/svg BCAL-DV-AMP051 22.3 mg/svg BCAL-DV-AMP051 and BCAL-DV-AMP052 212 mg/svg BCAL-DV-AMP051 90.2 mg/svg BCAL-DV-AMP051 31.2 mg/svg BCAL-DV-AMP051 and 171 mg/svg	BCAL-DV-AMP051 and BCAL-DV-AMP052 188 mg/svg 04/05/2024 BCAL-DV-AMP051 22.3 mg/svg 03/26/2024 BCAL-DV-AMP051 and BCAL-DV-AMP052 212 mg/svg 04/05/2024 BCAL-DV-AMP051 90.2 mg/svg 03/26/2024 BCAL-DV-AMP051 31.2 mg/svg 03/26/2024 BCAL-DV-AMP051 and 171 mg/svg 04/05/2024

See Exhibit F

17. Plaintiffs have provided the Defendant with actual notice of their infringement of the Asserted Patents. *See* Exhibit G.

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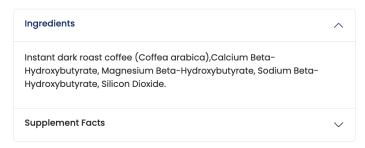
FIRST CLAIM FOR RELIEF

Patent Infringement – '952 Patent 35 U.S.C. §§ 1, et seq.

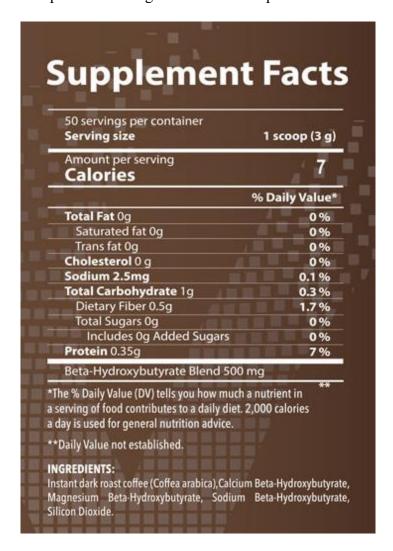
- 18. Plaintiffs incorporate and reallege the allegations of each of the preceding paragraphs as if fully set forth herein.
 - 19. Plaintiff AGS owns all rights in the '952 Patent.
- 20. Plaintiff Pruvit is the exclusive licensee of the '952 Patent in the relevant field of use.
- 21. On May 21, 2019, the '952 Patent, titled "Mixed salt compositions for maintaining or restoring electrolyte balance while producing elevated and sustained ketosis" A true and correct copy of the '952 Patent is attached as Exhibit A.
 - 22. Plaintiffs have marked their products in accordance with 35 U.S.C. § 287(a).
- 23. Plaintiffs have provided the Defendant with actual notice of the Asserted Patents. *See* Exhibit G.
- 24. Without license or authorization, Defendant makes, uses, imports, offers for sale, and/or sells the Accused Products containing compounds that infringe the '952 Patent.
- 25. On information and belief, the Accused Products are made with the concentrations of ingredients stated in the supplement facts for the Accused Products, including calcium beta-hydroxybutyrate, magnesium beta-hydroxybutyrate, and sodium beta-hydroxybutyrate, as stated on the Defendant's product packaging and product website:

Functional Beverages

V-KETOKAFE



https://vitalhealthglobal.com/usa/en/productos.html



https://vitalhealthglobal.com/usa/en/productos.html

26. On information and belief, the Accused Products contain calcium beta-hydroxybutyrate, magnesium beta-hydroxybutyrate, and sodium beta-hydroxybutyrate in a supplement product as reflected by the testing below.

Work Order: CHSG240322-007 Axcess Global Sciences LLC Received Date: 03/22/2024 Client: 8688 Ruffian Lane, Suite C

P.O. #:

Newburgh, IN 47630

Client Contact: Pam Peach

Comments:

Sample Num: 24CH03183 Lot Number: KETOK004

Client Sample Num: MexicoCoffe1 KetoKafe Comments: Serving Size: 3g

Analysis	Method Reference	Result	Unit	Analysis Date	Approval Date
Beta-Hydroxybutyrate (BHB)	BCAL-DV-AMP052 HPLC	561	mg/svg	04/03/2024	04/05/2024
Calcium	BCAL-DV-AMP051	30.5	mg/svg	03/26/2024	04/08/2024
Calcium 3-Hydroxybutyrate salt	BCAL-DV-AMP051 and BCAL-DV-AMP052	188	mg/svg	04/05/2024	04/05/2024
Magnesium	BCAL-DV-AMP051	22.3	mg/svg	03/26/2024	04/08/2024
Magnesium 3-Hydroxybutyrate salt	BCAL-DV-AMP051 and BCAL-DV-AMP052	212	mg/svg	04/05/2024	04/05/2024
Potassium	BCAL-DV-AMP051	90.2	mg/svg	03/26/2024	04/08/2024
Sodium	BCAL-DV-AMP051	31.2	mg/svg	03/26/2024	04/08/2024
Sodium 3-Hydroxybutyrate salt	BCAL-DV-AMP051 and BCAL-DV-AMP052	171	mg/svg	04/05/2024	04/05/2024

See Exhibit F

- 27. Representative claim 19 of the '952 Patent is reproduced below:
 - 19. A composition for maintaining or restoring electrolyte balance while promoting or sustaining ketosis in a mammal, the composition comprising:
 - a beta-hydroxybutyrate mixed salt formulated from a plurality of different cations and a single anion, wherein the single anion is betahydroxybutyrate, and wherein other anions are omitted from the betahydroxybutyrate mixed salt, the cations being formulated so as to

provide a biologically balanced set of cationic electrolytes upon administration to a mammal,

the beta-hydroxybutyrate mixed salt comprising at least three salts selected from the group consisting of:

10-70% by weight of sodium beta-hydroxybutyrate;

10-70% by weight of potassium beta-hydroxybutyrate;

10-70% by weight of calcium beta-hydroxybutyrate; and

10-70% by weight of magnesium beta-hydroxybutyrate,

wherein the beta-hydroxybutyrate mixed salt is in solid and/or powder form.

'952 Patent, claim 19.

- 28. As advertised in Defendant's product labels and listings, the Accused Products infringe at least representative claim 19 of the '952 Patent in the manner described below.
- 29. To the extent the preamble of claim 19 of the '952 Patent is limiting, the Accused Products meet the preamble of claim 19 as set forth below:
 - 19. A composition for maintaining or restoring electrolyte balance while promoting or sustaining ketosis in a mammal, the composition comprising:

a beta-hydroxybutyrate mixed salt formulated from a plurality of different cations and a single anion, wherein the single anion is beta-hydroxybutyrate, and wherein other anions are omitted from the beta-hydroxybutyrate mixed salt, the cations being formulated so as to provide a biologically balanced set of cationic electrolytes upon administration to a mammal,

the beta-hydroxybutyrate mixed salt comprising at least three salts selected from the group consisting of:

10-70% by weight of sodium beta-hydroxybutyrate;

10-70% by weight of potassium beta-hydroxybutyrate;

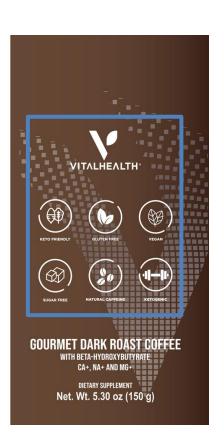
10-70% by weight of calcium beta-hydroxybutyrate; and

10-70% by weight of magnesium beta-hydroxybutyrate,

wherein the beta-hydroxybutyrate mixed salt is in solid and/or powder form

'952 Patent, claim 19.





https://vitalhealthglobal.com/usa/en/productos.html (See Exhibits D, E)

- 30. The Accused Products further meet the limitations of claim 19 as set forth below:
 - 19. A composition for maintaining or restoring electrolyte balance while promoting or sustaining ketosis in a mammal, the composition comprising:
 - a beta-hydroxybutyrate mixed salt formulated from a plurality of different cations and a single anion, wherein the single anion is betahydroxybutyrate, and wherein other anions are omitted from the

beta-hydroxybutyrate mixed salt, the cations being formulated so as to provide a biologically balanced set of cationic electrolytes upon administration to a mammal,

the beta-hydroxybutyrate mixed salt comprising at least three salts selected from the group consisting of:

10-70% by weight of sodium beta-hydroxybutyrate;

10-70% by weight of potassium beta-hydroxybutyrate;

10-70% by weight of calcium beta-hydroxybutyrate; and

10-70% by weight of magnesium beta-hydroxybutyrate,

wherein the beta-hydroxybutyrate mixed salt is in solid and/or powder form.

'952 Patent, claim 19.

50 servings per container Serving size	1 scoop (3 g)
Amount per serving Calories	7
Calonies	% Daily Value*
Total Fat 0g	0%
Saturated fat 0g	0%
Trans fat 0g	0%
Cholesterol 0 g	0%
Sodium 2.5mg	0.1%
Total Carbohydrate 1g	0.3 %
Dietary Fiber 0.5g	1.7 %
Total Sugars 0g	0%
Includes 0g Added Sugars	0%
Protein 0.35g	7%
Beta-Hydroxybutyrate Blend 50	00 mg
*The % Daily Value (DV) tells you how mu a serving of food contributes to a daily die a day is used for general nutrition advice.	et. 2,000 calories
**Daily Value not established.	

https://vitalhealthglobal.com/usa/en/productos.html

- 31. The Accused Products further meet the limitations of claim 19 as set forth below:
 - 19. A composition for maintaining or restoring electrolyte balance while promoting or sustaining ketosis in a mammal, the composition comprising:
 - a beta-hydroxybutyrate mixed salt formulated from a plurality of different cations and a single anion, wherein the single anion is betahydroxybutyrate, and wherein other anions are omitted from the betahydroxybutyrate mixed salt, the cations being formulated so as to

provide a biologically balanced set of cationic electrolytes upon administration to a mammal,

the beta-hydroxybutyrate mixed salt comprising at least three salts selected from the group consisting of:

10-70% by weight of sodium beta-hydroxybutyrate;

10-70% by weight of potassium beta-hydroxybutyrate;

10-70% by weight of calcium beta-hydroxybutyrate; and

10-70% by weight of magnesium beta-hydroxybutyrate,

wherein the beta-hydroxybutyrate mixed salt is in solid and/or powder form.

'952 Patent, claim 19.

Work Order: CHSG240322-007

Received Date: 03/22/2024

P.O. #:

Axcess Global Sciences LLC

Client: 8688 Ruffian Lane, Suite C

Newburgh, IN 47630

Client Contact: Pam Peach

Lot Number: KETOK004

Comments:

Sample Num: 24CH03183

Comments: Serving Size:	sg				
<u>Analysis</u>	Method Reference	Result	Unit	Analysis Date	Approval Date
Beta-Hydroxybutyrate (BHB)	BCAL-DV-AMP052 HPLC	561	mg/svg	04/03/2024	04/05/2024
Calcium	BCAL-DV-AMP051	30.5	mg/svg	03/26/2024	04/08/2024
Calcium 3-Hydroxybutyrate salt	BCAL-DV-AMP051 and	188	mg/svg	04/05/2024	04/05/2024
Magnesium	BCAL-DV-AMP051	22.3	mg/svg	03/26/2024	04/08/2024
Magnesium 3-Hydroxybutyrate salt	BCAL-DV-AMP051 and	212	mg/svg	04/05/2024	04/05/2024
Potassium	BCAL-DV-AMP051	90.2	mg/svg	03/26/2024	04/08/2024
Sodium	BCAL-DV-AMP051	31.2	mg/svg	03/26/2024	04/08/2024
Sodium 3-Hydroxybutyrate salt	BCAL-DV-AMP051 and BCAL-DV-AMP052	171	mg/svg	04/05/2024	04/05/2024

See Exhibit F

- 32. The Accused Products further meet the limitations of claim 19 as set forth below:
 - 19. A composition for maintaining or restoring electrolyte balance while promoting or sustaining ketosis in a mammal, the composition comprising:

a beta-hydroxybutyrate mixed salt formulated from a plurality of different cations and a single anion, wherein the single anion is beta-hydroxybutyrate, and wherein other anions are omitted from the beta-hydroxybutyrate mixed salt, the cations being formulated so as to provide a biologically balanced set of cationic electrolytes upon administration to a mammal,

the beta-hydroxybutyrate mixed salt comprising at least three salts selected from the group consisting of:

10-70% by weight of sodium beta-hydroxybutyrate;

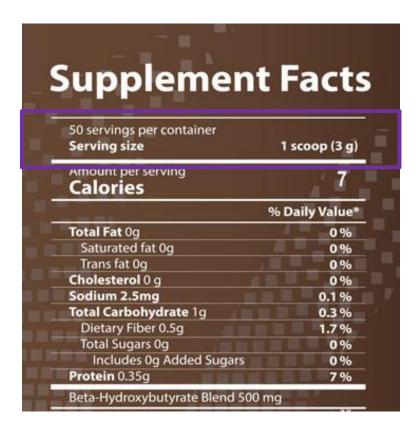
10-70% by weight of potassium beta-hydroxybutyrate;

10-70% by weight of calcium beta-hydroxybutyrate; and

10-70% by weight of magnesium beta-hydroxybutyrate,

wherein the beta-hydroxybutyrate mixed salt is in solid and/or powder form.

'952 Patent, claim 19.



https://vitalhealthglobal.com/usa/en/productos.html

- 33. Defendant has directly infringed claim 19 of the '952 Patent in the United States by making, using, offering for sale, selling, and/or importing the Accused Products in violation of 35 U.S.C. § 271(a). As such, Defendant is liable for direct infringement of the '952 Patent under 35 U.S.C. § 271(a).
- 34. Defendant has indirectly infringed the '952 Patent in this District and elsewhere in the United States by inducing others to make, use, offer for sale, import, and/or sell the Accused Products in violation of 35 U.S.C. § 271(b). Defendant has actual knowledge of its infringement of the '403 Patent. As such, Defendant is liable for indirect infringement of the '952 Patent under 35 U.S.C. § 271(b).
 - 35. Defendant's infringement of the '952 Patent is willful and this case is exceptional.

36. Plaintiffs have suffered harm as a result of Defendant's infringement of the '952 Patent, including in the form of lost profits and diverted sales and market share. Plaintiffs are therefore entitled to recover damages sustained as a result of Defendant's wrongful acts in an amount that is to be proven at trial.

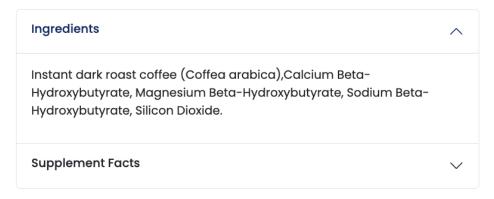
SECOND CLAIM FOR RELIEF Patent Infringement – '362 Patent 35 U.S.C. §§ 1, et seq.

- 37. Plaintiffs incorporate and reallege the allegations of each of the preceding paragraphs as if fully set forth herein.
 - 38. Plaintiff AGS owns all rights in the '362 Patent.
- 39. Plaintiff Pruvit is the exclusive licensee of the '362 Patent in the relevant field of use.
- 40. On June 1, 2021, the '362 Patent, titled "Beta-hydroxybutyrate mixed salt compositions and methods of use" was duly and legally issued. A true and correct copy of the '362 Patent is attached as Exhibit B.
 - 41. Plaintiffs have marked their products in accordance with 35 U.S.C. § 287(a).
- 42. Plaintiffs have provided the Defendant with actual notice of the Asserted Patents. *See* Exhibit G.
- 43. Without license or authorization, Defendant makes, uses, imports, offers for sale, and/or sells the Accused Products containing compounds that infringe the '362 Patent.
- 44. On information and belief, the Accused Products are made with the concentrations of ingredients stated in the supplement facts for the Accused Products, including calcium beta-

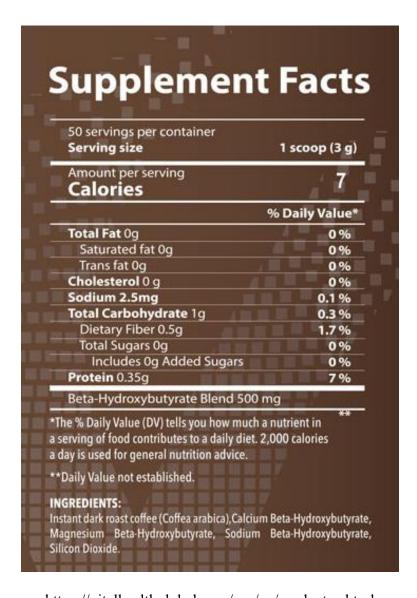
hydroxybutyrate, magnesium beta-hydroxybutyrate, and sodium beta-hydroxybutyrate, as stated on the Defendant's product packaging and product website:

Functional Beverages

V-KETOKAFE



https://vitalhealthglobal.com/usa/en/productos.html



https://vitalhealthglobal.com/usa/en/productos.html

45. On information and belief, the Accused Products contain calcium beta-hydroxybutyrate, magnesium beta-hydroxybutyrate, and sodium beta-hydroxybutyrate in a supplement product as reflected by the testing below.

Work Order: CHSG240322-007

Received Date: 03/22/2024

P.O. #:

Axcess Global Sciences LLC

Client: 8688 Ruffian Lane, Suite C

Newburgh, IN 47630

Client Contact: Pam Peach

Comments:

Sample Num: 24CH03183 Lot Number: KETOK004

Client Sample Num: MexicoCoffe1 KetoKafe
Comments: Serving Size: 3g

<u>Analysis</u>	Method Reference	Result	Unit	Analysis Date	Approval Date
Beta-Hydroxybutyrate (BHB)	BCAL-DV-AMP052 HPLC	561	mg/svg	04/03/2024	04/05/2024
Calcium	BCAL-DV-AMP051	30.5	mg/svg	03/26/2024	04/08/2024
Calcium 3-Hydroxybutyrate salt	BCAL-DV-AMP051 and BCAL-DV-AMP052	188	mg/svg	04/05/2024	04/05/2024
Magnesium	BCAL-DV-AMP051	22.3	mg/svg	03/26/2024	04/08/2024
Magnesium 3-Hydroxybutyrate salt	BCAL-DV-AMP051 and BCAL-DV-AMP052	212	mg/svg	04/05/2024	04/05/2024
Potassium	BCAL-DV-AMP051	90.2	mg/svg	03/26/2024	04/08/2024
Sodium	BCAL-DV-AMP051	31.2	mg/svg	03/26/2024	04/08/2024
Sodium 3-Hydroxybutyrate salt	BCAL-DV-AMP051 and BCAL-DV-AMP052	171	mg/svg	04/05/2024	04/05/2024

See Exhibit F

- 46. Representative claim 1 of the '362 Patent is reproduced below:
 - 1. A composition for increasing blood ketone level in a subject, comprising:

at least three beta-hydroxybutyrate salts selected from:

sodium beta-hydroxybutyrate;

potassium beta-hydroxybutyrate;

calcium beta-hydroxybutyrate; and

magnesium beta-hydroxybutyrate;

wherein the composition is in solid and/or powder form,

wherein the composition is free of medium chain fatty acids having 6 to 12 carbons and glycerides or other esters thereof.

'362 Patent, claim 1.

- 47. As advertised in Defendant's product labels and listings, the Accused Products infringe at least representative claim 1 of the '362 Patent in the manner described below.
- 48. To the extent the preamble of claim 1 is limiting, the Accused Products meet the preamble of claim 1 as set forth below:
 - 1. A composition for increasing blood ketone level in a subject, comprising:

at least three beta-hydroxybutyrate salts selected from:

sodium beta-hydroxybutyrate;

potassium beta-hydroxybutyrate;

calcium beta-hydroxybutyrate; and

magnesium beta-hydroxybutyrate;

wherein the composition is in solid and/or powder form,

wherein the composition is free of medium chain fatty acids having 6 to 12 carbons and glycerides or other esters thereof.

'362 Patent, claim 1.





https://vitalhealthglobal.com/usa/en/productos.html (See Exhibits D, E)

- 49. The Accused Products further meet the limitations of claim 1 as set forth below:
 - 1. A composition for increasing blood ketone level in a subject, comprising:

at least three beta-hydroxybutyrate salts selected from:

sodium beta-hydroxybutyrate;

potassium beta-hydroxybutyrate;

calcium beta-hydroxybutyrate; and

magnesium beta-hydroxybutyrate;

wherein the composition is in solid and/or powder form,

wherein the composition is free of medium chain fatty acids having 6 to 12 carbons and glycerides or other esters thereof.

'362 Patent, claim 1.

Work Order: CHSG240322-007

Received Date: 03/22/2024
P.O. #:

Axcess Global Sciences LLC
8688 Ruffian Lane, Suite C
Newburgh, IN 47630

Client Contact: Pam Peach

Comments:

Sample Num: 24CH03183 Lot Number: KETOK004

Client Sample Num: MexicoCoffe1 KetoKafe Comments: Serving Size: 3g

<u>Analysis</u>	Method Reference	Result	Unit	Analysis Date	Approval Date
Beta-Hydroxybutyrate (BHB)	BCAL-DV-AMP052 HPLC	561	mg/svg	04/03/2024	04/05/2024
Calcium	BCAL-DV-AMP051	30.5	mg/svg	03/26/2024	04/08/2024
Calcium 3-Hydroxybutyrate salt	BCAL-DV-AMP051 and	188	mg/svg	04/05/2024	04/05/2024
Magnesium	BCAL-DV-AMP051	22.3	mg/svg	03/26/2024	04/08/2024
Magnesium 3-Hydroxybutyrate salt	BCAL-DV-AMP051 and	212	mg/svg	04/05/2024	04/05/2024
Potassium	BCAL-DV-AMP051	90.2	mg/svg	03/26/2024	04/08/2024
Sodium	BCAL-DV-AMP051	31.2	mg/svg	03/26/2024	04/08/2024
Sodium 3-Hydroxybutyrate salt	BCAL-DV-AMP051 and BCAL-DV-AMP052	171	mg/svg	04/05/2024	04/05/2024

See Exhibit F

'403 Patent, claim 1.

- 50. The Accused Products further meet the limitations of claim 1 as set forth below:
 - 1. A composition for increasing blood ketone level in a subject, comprising:

at least three beta-hydroxybutyrate salts selected from:

sodium beta-hydroxybutyrate;

potassium beta-hydroxybutyrate;

calcium beta-hydroxybutyrate; and

magnesium beta-hydroxybutyrate;

wherein the composition is in solid and/or powder form,

wherein the composition is free of medium chain fatty acids having 6 to 12 carbons and glycerides or other esters thereof.









https://vitalhealthglobal.com/usa/en/productos.html (See Exhibits D, E)

- 51. Defendant has directly infringed claim 1 of the '362 Patent in the United States by making, using, offering for sale, selling, and/or importing the Accused Products in violation of 35 U.S.C. § 271(a). As such, Defendant is liable for direct infringement of the '362 Patent under 35 U.S.C. § 271(a).
- 52. Defendant has indirectly infringed the '362 Patent in this District and elsewhere in the United States by inducing others to make, use, offer for sale, import, and/or sell the Accused

Products in violation of 35 U.S.C. § 271(b). Defendant has actual knowledge of its infringement of the '362 Patent. As such, Defendant is liable for indirect infringement of the '362 Patent under 35 U.S.C. § 271(b).

- 53. Defendant's infringement of the '362 Patent is willful and this case is exceptional.
- 54. Plaintiffs have suffered harm as a result of Defendant's infringement of the '362 Patent, including in the form of lost profits and diverted sales and market share. Plaintiffs are therefore entitled to recover damages sustained as a result of Defendant's wrongful acts in an amount that is to be proven at trial.

THIRD CLAIM FOR RELIEF Patent Infringement – '403 Patent 35 U.S.C. §§ 1, et seg.

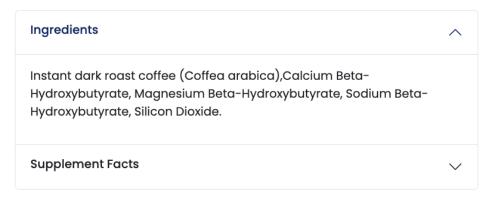
- 55. Plaintiffs incorporate and reallege the allegations of each of the preceding paragraphs as if fully set forth herein.
 - 56. Plaintiff AGS owns all rights in the '403 Patent.
- 57. Plaintiff Pruvit is the exclusive licensee of the '403 Patent in the relevant field of use.
- 58. On February 8, 2022, the '403 Patent, titled "Beta-hydroxybutyrate mixed salt compositions and methods of use" was duly and legally issued. A true and correct copy of the '403 Patent is attached as Exhibit C.
 - 59. Plaintiffs have marked their products in accordance with 35 U.S.C. § 287(a).
- 60. Plaintiffs have provided the Defendant with actual notice of the Asserted Patents.

 See Exhibit G.

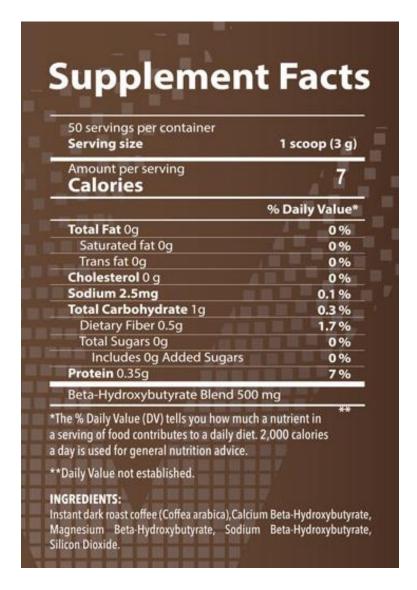
- 61. Without license or authorization, Defendant makes, uses, imports, offers for sale, and/or sells the Accused Products containing compounds that infringe the '403 Patent.
- 62. On information and belief, the Accused Products are made with the concentrations of ingredients stated in the supplement facts for the Accused Products, including calcium beta-hydroxybutyrate, magnesium beta-hydroxybutyrate, and sodium beta-hydroxybutyrate, as stated on the Defendant's product packaging and product website:

Functional Beverages

V-KETOKAFE



https://vitalhealthglobal.com/usa/en/productos.html



https://vitalhealthglobal.com/usa/en/productos.html

63. On information and belief, the Accused Products contain calcium beta-hydroxybutyrate, magnesium beta-hydroxybutyrate, and sodium beta-hydroxybutyrate in a supplement product as reflected by the testing below.

Work Order: CHSG240322-007 Axcess Global Sciences LLC
Received Date: 03/22/2024 Client: 8688 Ruffian Lane, Suite C

P.O. #:

Newburgh, IN 47630

Client Contact: Pam Peach

Comments:

Sample Num: 24CH03183 Lot Number: KETOK004

Client Sample Num: MexicoCoffe1 KetoKafe Comments: Serving Size: 3g

<u>Analysis</u>	Method Reference	Result	Unit	Analysis Date	Approval Date
Beta-Hydroxybutyrate (BHB)	BCAL-DV-AMP052 HPLC	561	mg/svg	04/03/2024	04/05/2024
Calcium	BCAL-DV-AMP051	30.5	mg/svg	03/26/2024	04/08/2024
Calcium 3-Hydroxybutyrate salt	BCAL-DV-AMP051 and BCAL-DV-AMP052	188	mg/svg	04/05/2024	04/05/2024
Magnesium	BCAL-DV-AMP051	22.3	mg/svg	03/26/2024	04/08/2024
Magnesium 3-Hydroxybutyrate salt	BCAL-DV-AMP051 and BCAL-DV-AMP052	212	mg/svg	04/05/2024	04/05/2024
Potassium	BCAL-DV-AMP051	90.2	mg/svg	03/26/2024	04/08/2024
Sodium	BCAL-DV-AMP051	31.2	mg/svg	03/26/2024	04/08/2024
Sodium 3-Hydroxybutyrate salt	BCAL-DV-AMP051 and BCAL-DV-AMP052	171	mg/svg	04/05/2024	04/05/2024

See Exhibit F

- 64. Representative claim 1 of the '403 Patent is reproduced below:
 - 1. A composition for increasing ketone level in a subject, comprising:

a plurality of beta-hydroxybutyrate salts comprised of:

at least one beta-hydroxybutyrate salt selected from:

calcium beta-hydroxybutyrate; and

magnesium beta-hydroxybutyrate; and

at least one other beta-hydroxybutyrate salt selected from:

sodium beta-hydroxybutyrate;

potassium beta-hydroxybutyrate;

calcium beta-hydroxybutyrate;
magnesium beta-hydroxybutyrate; and

amino acid salts of beta-hydroxybutyrate,

wherein the beta-hydroxybutyrate salts comprise at least 20% by total weight of calcium beta-hydroxybutyrate and/or magnesium beta-hydroxybutyrate,

wherein the composition is in solid and/or powder form,

wherein the composition is free of medium chain fatty acids having 6 to 12 carbons and glycerides or other esters thereof.

'403 Patent, claim 1.

- 65. As advertised in Defendant's product labels and listings, the Accused Products infringe at least representative claim 1 of the '403 Patent in the manner described below.
- 66. To the extent the preamble of claim 1 is limiting, the Accused Products meet the preamble of claim 1 as set forth below:
 - 1. A composition for increasing ketone level in a subject, comprising: a plurality of beta-hydroxybutyrate salts comprised of:

at least one beta-hydroxybutyrate salt selected from:

calcium beta-hydroxybutyrate; and

magnesium beta-hydroxybutyrate; and

at least one other beta-hydroxybutyrate salt selected from:

sodium beta-hydroxybutyrate;

potassium beta-hydroxybutyrate;

calcium beta-hydroxybutyrate;

magnesium beta-hydroxybutyrate; and

amino acid salts of beta-hydroxybutyrate,

wherein the beta-hydroxybutyrate salts comprise at least 20% by total weight of calcium beta-hydroxybutyrate and/or magnesium beta-hydroxybutyrate,

wherein the composition is in solid and/or powder form,

wherein the composition is free of medium chain fatty acids having 6 to 12 carbons and glycerides or other esters thereof.

'403 Patent, claim 1.





https://vitalhealthglobal.com/usa/en/productos.html (See Exhibits D, E)

- 67. The Accused Products further meet the limitations of claim 1 as set forth below:
 - 1. A composition for increasing ketone level in a subject, comprising:

a plurality of beta-hydroxybutyrate salts comprised of:

at least one beta-hydroxybutyrate salt selected from:

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calcium beta-hydroxybutyrate; and
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magnesium beta-hydroxybutyrate; and

at least one other beta-hydroxybutyrate salt selected from:

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sodium beta-hydroxybutyrate;
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potassium beta-hydroxybutyrate;

calcium beta-hydroxybutyrate;

magnesium beta-hydroxybutyrate; and

amino acid salts of beta-hydroxybutyrate,

wherein the beta-hydroxybutyrate salts comprise at least 20% by total weight of calcium beta-hydroxybutyrate and/or magnesium beta-hydroxybutyrate,

wherein the composition is in solid and/or powder form,

wherein the composition is free of medium chain fatty acids having 6 to 12 carbons and glycerides or other esters thereof.

Work Order: CHSG240322-007

Received Date: 03/22/2024

P.O. #:

Axcess Global Sciences LLC

Client: 8688 Ruffian Lane, Suite C

Newburgh, IN 47630

Client Contact: Pam Peach

Comments:

Sample Num: 24CH03183 Lot Number: KETOK004

Client Sample Num: MexicoCoffe1 KetoKafe Comments: Serving Size: 3g

<u>Analysis</u>	Method Reference	Result	Unit	Analysis Date	Approval Date
Beta-Hydroxybutyrate (BHB)	BCAL-DV-AMP052 HPLC	561	mg/svg	04/03/2024	04/05/2024
Calcium	BCAL-DV-AMP051	30.5	mg/svg	03/26/2024	04/08/2024
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Magnesium	BCAL-DV-AMP051	22.3	mg/svg	03/26/2024	04/08/2024
Magnesium 3-Hydroxybutyrate salt	BCAL-DV-AMP051 and	212	mg/svg	04/05/2024	04/05/2024
Potassium	BCAL-DV-AMP051	90.2	mg/svg	03/26/2024	04/08/2024
Sodium	BCAL-DV-AMP051	31.2	mg/svg	03/26/2024	04/08/2024
Sodium 3-Hydroxybutyrate salt	BCAL-DV-AMP051 and BCAL-DV-AMP052	171	mg/svg	04/05/2024	04/05/2024

See Exhibit F

- 68. The Accused Products further meet the limitations of claim 1 as set forth below:
 - 1. A composition for increasing ketone level in a subject, comprising:

a plurality of beta-hydroxybutyrate salts comprised of:

at least one beta-hydroxybutyrate salt selected from:

calcium beta-hydroxybutyrate; and

magnesium beta-hydroxybutyrate; and

at least one other beta-hydroxybutyrate salt selected from:

sodium beta-hydroxybutyrate;

potassium beta-hydroxybutyrate;

calcium beta-hydroxybutyrate;

magnesium beta-hydroxybutyrate; and

amino acid salts of beta-hydroxybutyrate,

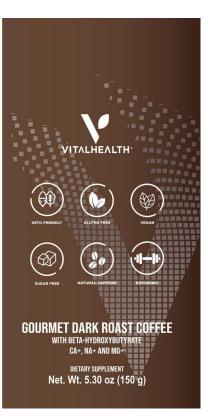
wherein the beta-hydroxybutyrate salts comprise at least 20% by total weight of calcium beta-hydroxybutyrate and/or magnesium beta-hydroxybutyrate,

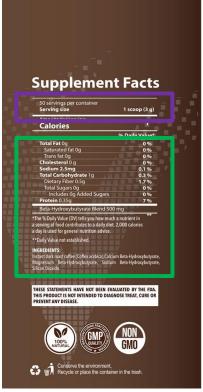
wherein the composition is in solid and/or powder form,

wherein the composition is free of medium chain fatty acids having 6 to 12 carbons and glycerides or other esters thereof.

'403 Patent, claim 1.









https://vitalhealthglobal.com/usa/en/productos.html (See Exhibits D, E)

- 69. The Defendant has directly infringed claim 1 of the '403 Patent in the United States by making, using, offering for sale, selling, and/or importing the Accused Products in violation of 35 U.S.C. § 271(a). As such, Defendant is liable for direct infringement of the '403 Patent under 35 U.S.C. § 271(a).
- 70. The Defendant has indirectly infringed the '403 Patent in this District and elsewhere in the United States by inducing others to make, use, offer for sale, import, and/or sell the Accused Products in violation of 35 U.S.C. § 271(b). Defendant has actual knowledge of its infringement of the '403 Patent. As such, Defendant is liable for indirect infringement of the '403 Patent under 35 U.S.C. § 271(b).
- 71. The Defendant's infringement of the '403 Patent is willful and this case is exceptional.
- 72. Plaintiffs have suffered harm as a result of Defendant's infringement of the '403 Patent, including in the form of lost profits and diverted sales and market share. Plaintiffs are therefore entitled to recover damages sustained as a result of Defendant's wrongful acts in an amount that is to be proven at trial.

PRAYER FOR RELIEF

Wherefore, Plaintiffs respectfully prays that the Court enter judgment in its favor and award the following relief against Defendant:

A. A judgment that Defendant infringed the '952 Patent directly and indirectly by inducement;

- B. A judgment that Defendant infringed the '403 Patent directly and indirectly by inducement;
- C. A judgment that Defendant infringed the '362 Patent directly and indirectly by inducement;
- D. A finding that the Defendant's conduct alleged herein was willful and that this case is exceptional;
- E. An order and judgment enjoining Defendant and its officers, directors, employees, agents, licensees, representatives, affiliates, related companies, servants, successors and assigns, and any and all persons acting in privity or in concert with any of them, from infringing the Asserted Patents;
- F. An award of actual damages in an amount to be determined at trial for patent infringement;
 - G. Plaintiff's costs and attorneys' fees;

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- H. A judgment for increased damages as allowed by law; and
- I. Any such other and further relief as the Court deems proper.

DEMAND FOR JURY TRIAL

Pursuant to Rule 38(b) of the Federal Rules of Civil Procedure, Plaintiffs demand a jury trial on all matters triable to a jury.

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DATED September 23, 2024.

Respectfully submitted,

CROWLEY | FLECK

By: /s/ Alaina M. Stedillie
Alaina M. Stedillie

WORKMAN NYDEGGER

Brian N. Platt (pro hac vice forthcoming) Collin D. Hansen (pro hac vice forthcoming)

Counsel for Plaintiff Axcess Global Sciences, LLC and Pruvit Ventures, Inc.